IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2327

THIS DOCUMENT RELATES TO:

Cases Identified in Exhibit A
attached hereto

ORDER ADOPTING
MEMORANDUM OPINION AND ORDER
(*Daubert* ruling re: Brian Raybon, M.D.)

On October 23, 2017, defendants filed a Notice of Adoption of Prior *Daubert* Motion Challenging the General-Causation Opinions of Brian Raybon, M.D. for Wave 6. [ECF No. 4854]. The court **ORDERS** that the Memorandum Opinion and Order (*Daubert* Motion re: Brian Raybon, M.D.) [ECF No. 2687] entered on August 30, 2016 as to the Ethicon Wave 1 cases is **ADOPTED** in the Wave 6[1] cases identified in Exhibit A. The Memorandum Opinion and Order (*Daubert* Motion re: Brian Raybon, M.D.) is attached hereto as Exhibit B.

The court **DIRECTS** the Clerk to file a copy of this Order Adopting Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 6 cases identified in the Exhibit attached hereto.

ENTER: July 31, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

[1] On Exhibit A, I have marked through cases that are closed on the inactive docket or assigned to another District Judge and any cases that could not be identified because of an error in the style or case number.

EXHIBIT A

LIST OF CASES TO WHICH MOTION TO EXCLUDE GENERAL-CAUSATION TESTIMONY OF BRIAN RAYBON, M.D. APPLIES

1. ~~*Tammy Dillbeck v. Ethicon, Inc., et al.*, Civil Action No. 2:13-cv-02638 (Prolift Total, TVT-O*)~~

2. ~~*Margo Ellis, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-09097 (TVT*)~~

3. ~~*Monda Erskine, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-09686 (Prolift Total, TVT-S*)~~

4. ~~*Teresa Hamlin v. Ethicon, Inc., et al.*, Civil Action No. 2:13-cv-00522 (Prolift Posterior)~~

5. ~~*Christine Heatherman, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-09245 (TVT*)~~

6. ~~*Theresse Henry v. Ethicon, Inc., et al.*, Civil Action No. 2:13-cv-00253 (Gynemesh PS, TVT-O*)~~

7. ~~*Linda F. Hooper v. Ethicon, Inc., et al.*, Civil Action No. 2:13-cv-01686 (Prolift +M Posterior)~~

8. ~~*Patricia Jacobs v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-09034 (Gynemesh PS)~~

9. ~~*Ruby Lawler, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:13-cv-01046 (TVT*)~~

10. ~~*Jackie McWherter v. Ethicon, Inc., et al.*, Civil Action No. 2:13-cv-02067 (Prolift +M Anterior, TVT-O*)~~

11. ~~*Joyce Nurdin, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-09096 (Prolift +M Anterior)~~

12. ~~*Sue Sisk, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:13-cv-00780 (TVT*)~~

*Dr. Raybon offers no opinions on the TVT, TVT-O, or TVT-S, and therefore the general-causation opinions he offers here do not apply to those products in *Dillbeck*, *Ellis*, *Erskine*, *Heatherman*, *Henry*, *Lawler*, *McWherter*, and *Sisk*.

**Defendants reserve the right to supplement this list should any plaintiff designate Dr. Raybon as a general-causation expert in MDL Wave 6.

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2327

THIS DOCUMENT RELATES TO:

Cases Identified in the Exhibit
Attached Hereto

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Brian Raybon, M.D.)

Pending before the court is the Motion to Exclude General-Causation Testimony of Brian Raybon, M.D. [ECF No. 2115] filed by the defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon"). The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

Litigation in Products Liability Cases 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order ("PTO") No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.[1]

II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert*'s core considerations for assessing expert

[1] Ethicon identified the Wave 1 cases affected by this Motion in its attached Exhibit A [ECF No. 2115-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert

testimony may be evaluated at trial. At trial, the expert testimony will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of "junk science" looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court's prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these

standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

> (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts "principles and methodology" above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g.*, *Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

Dr. Raybon is a board-certified physician in obstetrics and gynecology, specializing in female pelvic floor medicine and reconstructive surgery. Ethicon seeks

exclusion of his expert testimony on several grounds.

a. Complications

Ethicon seeks to exclude all of Dr. Raybon's general causation opinions relating to alleged medical complications. Dr. Raybon's expert report identifies numerous complications that he states he has seen in his patients (e.g., chronic pelvic pain, nerve damage, and dyspareunia). Ethicon challenges Dr. Raybon's qualifications to offer these opinions because Dr. Raybon is not specialized in etiology and vaginal pain.

Dr. Raybon is a board-certified physician in obstetrics and gynecology, specializing in female pelvic medicine and reconstructive surgery. Dr. Raybon currently serves as a clinical assistant professor at the Medical College of Georgia, and he has implanted and explanted many POP mesh products, including the Prolift. As a treating physician who has extensive experience treating patients suffering from POP by implanting and explanting various mesh devices, I find that Dr. Raybon has the requisite qualifications to opine on the alleged association between complications and relevant mesh devices. Ethicon's Motion is **DENIED** on this point.

b. Warnings

Ethicon claims Dr. Raybon is not qualified to offer expert testimony about product warnings, which includes expert testimony about the adequacy of the relevant Instructions for Use ("IFU"). According to Ethicon, Dr. Raybon is not an expert in the development of warning labels and thus is not qualified to offer expert testimony about warnings. Dr. Raybon is not an expert in the development of warning

labels. While an expert who is an obstetrician and gynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU. *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015). Dr. Raybon does not possess the additional expertise to offer expert testimony about what an IFU should or should not include. Accordingly, Dr. Raybon's expert testimony about these matters is **EXCLUDED**.

c. **Alternative Design**

Ethicon asks the court to exclude Dr. Raybon's expert testimony about safer alternatives to Ethicon mesh products as unreliable. Upon review, I am without information sufficient to determine whether this testimony is reliable or unreliable at this time. By necessity, expert testimony of this sort relies greatly on experience.

In the abstract, experience—on its own or accompanied by little else—is a reliable basis for expert testimony. *See Kumho*, 526 U.S. at 156. But the reliability inquiry must probe into the relationship between the experience and the expert testimony:

> If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.

Fed. R. Evid. 702 advisory committee's note to 2000 amendment. Here, the court does not have enough information to judge the reliability or relevance of Dr. Raybon's particular experience.

In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on this issue. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

d. Competency of Other Physicians

Ethicon challenges Dr. Raybon's opinions regarding the adequacy of Ethicon's physician training programs, the overall difficulty of a mesh implantation procedure, and the ability of other physicians who were inexperienced at the time of surgery. Instead of challenging Dr. Raybon's opinions on qualification or reliability grounds, Ethicon argues that Dr. Raybon's opinions on these topics are irrelevant, speculative, and potentially misleading. The plaintiffs respond by pointing out that Ethicon has consistently raised the defense that complications are actually attributable to surgeon error, not the design of the product. Thus, the plaintiffs' offer of rebuttal testimony on these points would appear to be relevant. At this stage in the proceedings, however, I find that this issue would be better resolved in the actual context in which it may arise during trial. Accordingly, I **RESERVE** ruling on these matters.

e. Clinical Studies Opinions

Ethicon seeks to exclude Dr. Raybon's opinions regarding his analysis of two clinical studies, which he uses to support his risk-benefit opinions. Ethicon argues that Dr. Raybon is unqualified to offer any opinions on clinical studies because of a prior ruling from this court. *See Wise v. C. R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL

521202, at *16–17 (S.D. W. Va. Feb. 7, 2015). In *Wise*, however, I found Dr. Raybon unqualified to offer opinions about the appropriate testing a medical device manufacturer should undertake. *Id.* Here, Dr. Raybon is simply reviewing studies and relying on their results to support his opinion. As a treating physician, Dr. Raybon is perfectly qualified to review relevant medical literature to form an opinion on the possible risks and benefits of the devices he regularly uses in his practice. To the extent that Ethicon believes that Dr. Raybon "cherry picked" findings contained in certain clinical studies, it is free to cross-examine Dr. Raybon on the issue. Ethicon's Motion is **DENIED** on this point.

Dr. Raybon's use of the phrase "unacceptable risk," however, is unsupported. Dr. Raybon does not disclose any metric or standard he used to determine when a risk becomes "unacceptable." Accordingly, Dr. Raybon's opinions regarding "unacceptable risks" are **EXCLUDED**.

f. Certain Complications Not Presented in This Case

Ethicon next challenges Dr. Raybon's general causation opinions regarding infections, fistulae, and abscesses that allegedly occur when mesh devices are implanted through the vagina. Ethicon argues that these opinions should be excluded to the extent that the plaintiffs in the three listed cases for which Dr. Raybon is an expert did not suffer these complications. In other words, Ethicon argues that these opinions do not fit the facts of the three cases. The plaintiffs respond by stating only that this issue is better suited for a motion in limine. I disagree. Dr. Raybon's opinions cannot help the trier of fact to understand evidence or determine a fact in issue if the

relevant plaintiffs did not experience the discussed complications. Fed. R. Evid. 702. To the extent any of the plaintiffs in the three listed cases for which Dr. Raybon is an expert did not experience infections, fistulae, or abscesses, Dr. Raybon's opinions on these topics are **EXCLUDED**.

V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard*, 81 F.3d at 920 ("[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value."). Delving into complex and lengthy testimony about regulatory compliance could

inflate the perceived importance of compliance and lead jurors "to erroneously conclude that regulatory compliance proved safety." *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon's compliance with design control and risk management standards. Some of this testimony involves the FDA's quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here. To the extent any of these matters apply to this expert or were addressed in the Motion, the Motion is **DENIED**.

First, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from

using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

Third, many of the motions also ask the court to require an expert to offer testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of

Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

Finally, in some of the *Daubert* motions, without identifying the expert testimony to be excluded, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

VI. Conclusion

The court **DENIES in part**, **GRANTS in part**, and **RESERVES in part** the Motion to Exclude General-Causation Testimony of Brian Raybon, M.D. [ECF No. 2115].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: August 30, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE